

**Amendments To The Drawings:**

The attached new drawing sheet includes Figure 20 as described in the application at least at page 5, lines 19-20 and page 16, lines 1-24.

**Remarks**

This Amendment is in response to the Office Action dated **June 30, 2006**. Claims 1-37 are pending in this application. The Office Action rejected claims 1-4 and 14 under 35 USC § 102 over Denardo (US 6165194); rejected claims 1, 8, 9, 11, 14, 24, 26 and 36 under 35 USC § 102 over Stinson et al. (US 6340367; hereinafter “Stinson”); rejected claim 37 under 35 USC § 102 over Thompson et al. (US 5921978; hereinafter “Thompson”); rejected claims 5 and 15-23 under 35 USC § 103 over Denardo; rejected claims 28 and 30-33 under 35 USC § 103 over Stinson in view of Thompson; rejected claims 6-10 and 12 under 35 USC § 103 over Denardo in view of Stack et al. (US 6264671; hereinafter “Stack”); rejected claim 13 under 35 USC § 103 over Denardo in view of Pacetti (US 6574497); rejected claim 29 under 35 USC § 103 over Stinson in view of Thompson and further in view of Pacetti; rejected claims 25 and 27 under 35 USC § 103 over Stinson in view of Clement et al. (US 5681336; hereinafter “Clement”); rejected claims 34 and 35 under 35 USC § 103 over Stinson in view of Thompson and further in view of Clement; and objected to the drawings.

By this Amendment, claims 1, 15, 36 and 37 are amended and Figure 20 is added. Applicant reserves the right to prosecute any cancelled subject matter in a subsequent patent application claiming priority to the immediate application. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

**Drawings**

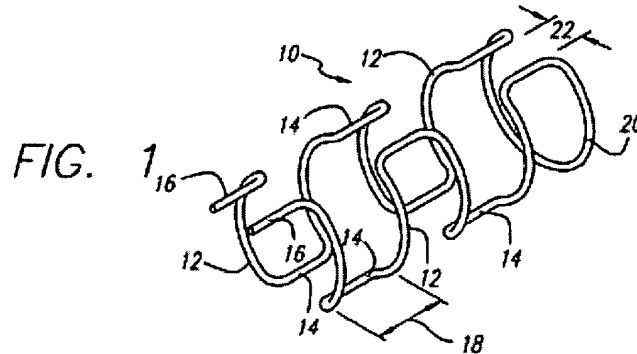
The Office Action objects to the drawings. A new drawing sheet is submitted herewith showing Figure 20 as described in the application. This Figure was inadvertently omitted from the application at the time of filing due to a clerical error. No new matter has been added. Figure 20 is fully described in the application at least at page 5, lines 19-20 and page 16, lines 1-24. Figure 20 is further supported by US 6179851 (see e.g. Figure 6), which was incorporated by reference (see page 16, lines 10-13). Accordingly, Applicant requests withdrawal of the objection to the drawings.

**Claim Rejections – 35 USC § 102 (Denardo)**

The Office Action rejected claims 1-4 and 14 under 35 USC § 102 over Denardo.

Claim 1 requires a medical device and a marker wire, “at least a portion of the marker wire defining the perimeter of a closed area, the closed area having a length that is less than the length of the medical device.”

Denardo discloses a flow modifier formed from a shape memory material. See column 2, lines 10-12 and Figure 1, provided below. The wire from which the device is made can be a stranded cable, which can include a radiopaque strand. See column 4, lines 35-38.



Any radiopaque strand included in the Denardo device would not define the perimeter of a closed area, as required by claim 1. As shown in Figure 1, the end portions 16 of the Denardo device do not meet, and therefore any radiopaque strand included in the device cannot define the perimeter of a closed area. Even when a delivery device is connected to the end portions 16, thereby bridging the gap between the end portions 16 to complete a perimeter, the radiopaque strand would not extend around the complete perimeter because the radiopaque strand terminates at the separated end portions 16.

Therefore, Applicant asserts that Denardo does not disclose or suggest all of the limitations of independent claim 1, and claim 1 is patentable over Denardo under 35 USC § 102. Claims 2-4 and 14 depend from claim 1 and are patentable over Denardo for at least the reasons discussed with respect to claim 1. Accordingly, Applicant requests withdrawal of the rejections under 35 USC § 102 over Denardo.

#### **Claim Rejections – 35 USC § 102 (Stinson)**

The Office Action rejected claims 1, 8, 9, 11, 14, 24, 26 and 36 under 35 USC § 102 over Stinson.

Independent claims 1 and 36 each require a marker wire that is permanently

coupled to the medical device.

Stinson teaches a temporary and retrievable radiopaque marker that is removably-attached to an implantable endoprosthesis. See, e.g. Abstract.

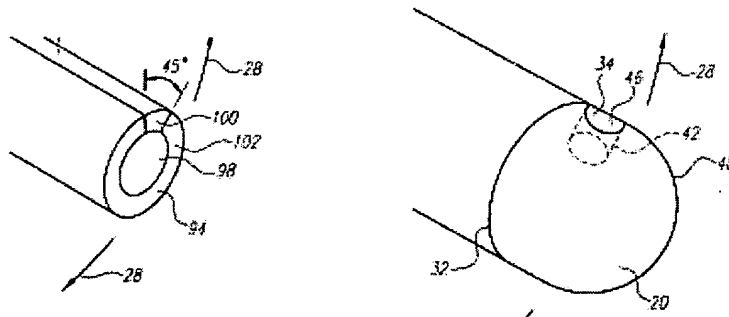
Therefore, Applicant asserts that Stinson does not disclose or suggest all of the limitations of independent claims 1 and 36, and that claims 1 and 36 are patentable over Stinson under 35 USC § 102. Claims 8, 9, 11, 14, 24 and 26 depend from claim 1 and are patentable over Stinson for at least the reasons discussed with respect to claim 1. Accordingly, Applicant requests withdrawal of the rejections under 35 USC § 102 over Stinson.

### **Claim Rejections – 35 USC § 102 (Thompson)**

The Office Action rejected claim 37 under 35 USC § 102 over Thompson.

Claim 37 requires a rotational marker comprising a wire loop.

Thompson discloses radiopaque markers in various shapes, such as a plug 34 or a stripe 100. See, e.g., column 5, lines 4-6 and column 6, lines 51-54 and Figs. 2 and 11, reproduced below.



Thompson does not disclose or suggest a radiopaque marker made from a wire loop, as required by claim 37. Therefore, Applicant asserts that Thompson does not disclose or suggest all of the limitations of independent claim 37, and that claim 37 is patentable over Thompson under 35 USC § 102. Accordingly, Applicant requests withdrawal of the rejection.

### **Claim Rejections – 35 USC § 103 (Denardo)**

The Office Action rejected, under 35 USC § 103, claims 5 and 15-23 over Denardo; claims 6-10 and 12 over Denardo in view of Stack; and claim 13 over Denardo in view

of Pacetti.

Amendments made to claim 1 are believed to render these rejections moot, and withdrawal of the rejections under 35 USC § 103 is requested.

Further, Applicant asserts that a person of ordinary skill in the art would not have been motivated to modify Denardo as asserted in the Office Action.

As discussed above in the rejection under 35 USC § 102, Denardo discloses a flow modifier device formed from a shape memory cable, wherein a strand of the cable can be a radiopaque material. See e.g. column 2, lines 10-12 and column 4, lines 35-38. Thus, the shape of the radiopaque marker inherently follows the shape of the flow modifier device. Consequently, any change to the shape of the radiopaque marker would also create an equal change the overall shape of the flow modifier device.

A person of ordinary skill in the art would recognize that the primary function of the Denardo device is to act as a flow modifier, and that the inclusion of a radiopaque strand is of secondary importance to the primary function. Therefore, a person of ordinary skill in the art would not be motivated to change the shape of the Denardo radiopaque marker as a mere “design choice” as asserted in the Office Action because any such changes would also change the primary design of the device.

### **Claim Rejections – 35 USC § 103 (Stinson)**

The Office Action rejected, under 35 USC § 103, claims 28 and 30-33 over Stinson in view of Thompson; and claim 29 over Stinson in view of Thompson and further in view of Pacetti. These rejections are traversed.

Applicant asserts that these rejections have not been presented with the particularly required to establish a *prima facie* case of obviousness. The rejection does not discuss where each limitation of the rejected claims can be found in the applied references. The rejection does not recite any prior art motivation for modifying either of the Stinson or Thompson devices, and further does not apply the missing motivation by discussing a proposed change to one of the devices. The rejections simply state, for example, that it would be obvious to “combine Thompson et al. with Stinson et al. as both inventions are related to radiopaque marked medical devices.” See Office Action pages 3-4.

With respect to the teachings of the individual references, the rejection states that “Stinson et al. discloses the orientation of the marker wire as disclosed above.” See Office Action page 4. Independent claim 28 recites a “first marker comprising a marker strip” and a “second marker comprising a marker strip.” The rejection does not discuss where either Stinson or Thompson teaches separate first and second marker strips.

The rejection states that Thompson discloses “markers made of two different materials so that part of the marker provides a darker image.” See Office Action page 4. Applicant requests that the Examiner specify where in Thompson this teaching is disclosed. It is further unclear whether the Examiner is asserting that Thompson teaches a single marker made from two different materials, or two different markers wherein each marker is made from a single material.

Thompson discloses a catheter having a marker plug and a marker strip. See e.g. Figure 30. The two markers will inherently appear differently when viewed under fluoroscopy due to their different sizes and shapes. However, it is unclear how the teaching of a marker strip and a marker plug in a catheter, which could inherently be made from different materials, would motivate a person of ordinary skill in the art to modify the removable marker wire for an implantable endoprosthesis taught by Stinson.

It is further unclear how a person of ordinary skill in the art would modify the Stinson device using teachings in Thompson to arrive at a device meeting the limitations of the rejected claims absent a hindsight use of Applicant’s disclosure. Withdrawal of the rejections is requested.

#### **Claim Rejections – 35 USC § 103 (Clement)**

The Office Action rejected, under 35 USC § 103, claims 25 and 27 over Stinson in view of Clement; and claims 34 and 35 over Stinson in view of Thompson and further in view of Clement. These rejections are traversed.

Applicant asserts that these rejections have not been presented with the particularly required to establish a *prima facie* case of obviousness. The rejection does not discuss where each limitation of the rejected claims can be found in the applied references. The rejection does not recite any prior art motivation for modifying any of the devices. The rejections

simply state that it would be obvious to “combine Clement et al. with Stinson et al. and Thompson et al. as all the inventions...are directed towards radiopaque marked intravascular devices.” See Office Action page 6.

It is unclear how the teachings of Stinson’s removable marker wire and Thompson’s catheter markers would motivate a person of ordinary skill in the art to modify the Clement rotational ablation device. It is further unclear how the Clement device would be modified to arrive at a device meeting the limitations of the rejected claims absent a hindsight use of Applicant’s disclosure. Withdrawal of the rejections is requested.

### **Conclusion**

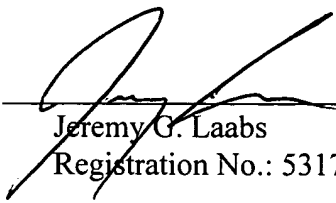
Based on at least the foregoing amendments and remarks, Applicants respectfully submit this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1-37 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants’ undersigned representative at the telephone number listed below.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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